



NEW JERSEY MEDICAL SCHOOL 8214 00 OCT 19 P2:05

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September 25, 2000

Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W. Room 615F
Washington, DC 20510

Dear Secretary Shalala,

My husband and I are residents of Mahwah, New Jersey. I am an audiologist and a full-time UMDNJ - New Jersey Medical School faculty member and the Director of the Audiology Service at University Hospital in Newark. In my faculty practice I dispense hearing aids and personally provide hearing care to over 1000 hearing aid users in the Newark, New Jersey area. In addition, my husband, a hearing instrument specialist, provides hearing aids and services to over 2000 individuals in his Ramsey, New Jersey office. Needless to say, we're vitally interested in the recent activity concerning FDA hearing aid regulations.

We are outraged that the U.S. Food and Drug Administration, after seven years of inaction, is rushing to publish in the twilight of the Clinton Administration a totally ill-conceived and misdirected proposed rule governing the sale of hearing aids. The newly proposed rule would abdicate federal FDA authority over hearing aid sales and allow the states to determine who will be qualified to dispense them and what tests should be administered before a hearing aid is purchased.

Presently, hearing instrument specialists, physicians and audiologists are essential and fully qualified professionals for a consumer's entry into our hearing health care system. If the FDA defers to the states, national organized audiology has indicated that it would endeavor to position audiologists as the gatekeeper on a state-by-state imperative. Such sole-source status could be achieved by lobbying states to require expensive pre-purchase hearing tests that only audiologists provide. By the way, these tests are NOT covered by Medicare when performed for the purposes of hearing aid fittings.

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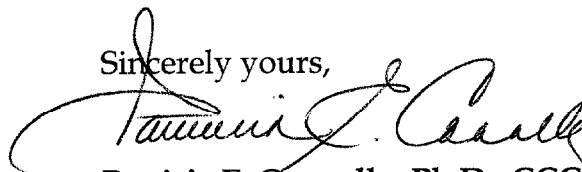
Obviously, this situation would greatly increase the cost of hearing aids and impede American's access to hearing care by effectively cutting in half the number of available providers through the disqualification of the non-audiologist hearing instrument specialist. Allowing any one provider "gatekeeper" status without unqualified medical data evincing that such a role is necessary for hearing health concerns would severely undermine public health and safety, impede access to necessary hearing health care services and would increase costs to the hearing impaired. There are 30 million Americans with hearing loss who need protection from the onerous provisions of this proposed rule.

This proposed rule is a predation on the non-audiologist hearing instrument specialists' businesses by organized audiology. I implore you to take the time required by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to carefully weigh the proposed regulation's negative impact on small business against the inevitable turf-wars that will be waged on 50 battlefronts by those who stand to make significant commercial and economic gains at the expense of other qualified providers should this regulation be passed.

On behalf of myself, my husband, our colleagues and the hearing impaired Americans in Newark and northern Bergen County, New Jersey that we serve, I urge you to use the discretion of your office and recommend that the FDA withdraw its proposed hearing aid ruling.

Thank you for this opportunity to address you with this very important concern.

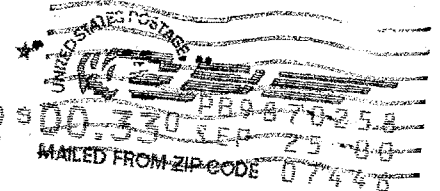
Sincerely yours,



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